DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Plenaxis
Docket No.: 2004E-0425

SEP 11 2006

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,843,901, filed by Praecis Pharmaceuticals, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Plenaxis (abarelix), the human drug product claimed by the patent.

The total length of the regulatory review period for Plenaxis (abarelix) is 2,566 days. Of this time, 1,487 days occurred during the testing phase and 1,079 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 17, 1996.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 17, 1996.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 12, 2000.

   FDA has verified the applicant's claim that the new drug application (NDA) for Plenaxis (abarelix) (NDA 21-320) was initially submitted on December 12, 2000.

3. The date the application was approved: November 25, 2003.

   FDA has verified the applicant's claim that NDA 21-320 was approved on November 25, 2003.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Maria Laccotripe-Zacharakis
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